



JAN 28 2005

Food and Drug Administration  
College Park, MD 20740

Martin J. Hahn  
Hogan & Hartson, L.L.P.  
555 Thirteenth Street, NW  
Washington, DC 20015-1109

Dear Mr. Hahn:

This responds, in part, to your letter dated December 3, 2004 ("December 3 letter") to William K. Hubbard, Associate Commissioner for Policy and Planning in the Food and Drug Administration (FDA) concerning FDA's October 7, 2004 letter ("October 7 letter") denying a health claim petition for crystalline glucosamine sulfate and reduced risk of osteoarthritis, joint deterioration, and related joint pain and limitation of function. First, you point out a factual error concerning the source of glucosamine that is being evaluated in studies sponsored by the National Institute of Health (NIH). Second, you argue that FDA mischaracterized and otherwise misstated the scientific credibility of the clinical studies that served as the foundation of your petition.

In the October 7 letter, FDA did identify the wrong source of glucosamine being used in the NIH sponsored studies. The correct source of glucosamine in those studies is glucosamine hydrochloride not glucosamine sulfate. We thank you for bringing this to our attention.

In the December 3 letter, you state that "FDA mischaracterized the data and made other inaccurate statements when discussing the credibility of the clinical studies supporting the efficacy of crystalline glucosamine sulfate." We disagree, and will provide a detailed response to your letter later this year.

Sincerely,

Barbara O. Schneeman, Ph.D.  
Director  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

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